Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Markup of H.R. 639, H.R. 471, H.R. ____, and H.R. ____
February 4, 2015

(As Prepared for Delivery)

Today, we are considering four important, bipartisan bills, but, for the sake of time, I will focus my remarks on H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act, which I introduced with Ranking Members Pallone and Green.

H.R. 639, as amended, seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act (CSA), and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster.

This Committee has worked diligently in the last several years to ensure that the FDA has the resources it needs to move new drugs more quickly through its approval process.

However, newly-approved drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can be marketed.

Unfortunately, under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly five-fold since 2000.

This bill would bring much needed certainty and predictability to the scheduling process and end the needless delays in patients' access to new therapies.

Senators Hatch and Whitehouse are working on companion legislation in the Senate, and we look forward to continuing conversations with them, as well as FDA and DEA, as this process moves forward.

I would urge all of my colleagues to support these bills, and I yield back the remainder of my time.

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